DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

Our STN: BL 103737/5031

JUN 0 9 2004

IDEC Pharmaceuticals Corporation
Attention: Nadine Cohen, Ph.D.
Senior Vice President, Regulatory Affairs
Biogen Idec, Incorporated
3030 Callan Road
San Diego, CA 92121

Dear Dr. Cohen:

Your request to supplement your biologics license application for Rituximab to revise the package insert to add a Hepatitis B Reactivation with Related Fulminant Hepatitis subsection to the WARNINGS section has been approved.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

The regulatory responsibility for review and continuing oversight for this product transferred from the Center for Biologics Evaluation and Research to the Center for Drug Evaluation and Research effective June 30, 2003. For further information about the transfer, please see http://www.fda.gov/cder/biologics/default.htm. Until further notice, however, all correspondence, except as provided elsewhere in this letter, should continue to be addressed to:

CBER Document Control Center
Attn: Office of Therapeutics Research and Review
Suite 200N (HFM-99)
1401 Rockville Pike
Rockville, Maryland 20852-1448

This information will be included in your biologics license application file.

Sincerely,

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Patricia Keegan, M.D.
Director
Division of Therapeutic Biological Oncology Products
Office of Drug Evaluation VI
Center for Drug Evaluation and Research

Enclosure: Package Insert Labeling

CONCURRENCE PAGE

Letter Type: LETTER: Approval (AP)
Summary Text: Clinical Supplmt. - Labeling Only
REVIEW COMPLETION REQUIRED BY: RIS

SS Data Check:

- **Place copy of Approval Ltr. with original signature concurrence page in Archival package behind the "Approval Materials" Tab after LAR (Licensing Action Recommendation).**

RIS Data Check:

- **Verify short summary - Ltr. & Submission screen should match.**
- **Check Letter for PMCs (if PMCs - add "PMCs - Approved With" special characteristic code.)**
- **Perform Review Completion Process**
- **Milestone: Confirm Approved Status**

cc: HFM-500/K. Weiss
HFM-585/E. Dye
HFM-570/P. Keegan
HFM-110/RIMs
DRMP BLA letter file
HFM-588/S. Sickafuse
HFM-570/H. Luksenburg
HFD-430/R. Pratt
HFD-430/S. Lu
HFD-013/Debbie Taub (ORP/DIDP)
HFD-013/Heidi Brubaker (ORP/DIDP)

History: Sickafuse:5-19-04:6-3-04:6-7-04:6-8-04: K. Townsend: 6.8.2004: 6.9.2004

File Name: (S:Sickafuse\Rituxan\labeling supplements\103737_5031\approval letter.doc)

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